UNITED STATES DISTRICT COURT FOR

THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR	

STATE OF NEVADA'S AMENDED COMPLAINT

[redacted]

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I. INTRODUCTION

1. The State of Nevada, through Attorney General Brian Sandoval, brings this action for monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits and punitive damages on behalf of the State of Nevada, and restitution on behalf of persons residing in Nevada who have paid inflated charges for medications based in whole or in part on defendants' use of the Average Wholesale Price Inflation Scheme detailed below.

2. Each of the defendants is or has been engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States, including Nevada. The principal payors for such prescription pharmaceuticals are federal and/or state governments (under, respectively, the Medicare and Medicaid Programs), private insurers and self-insured employers (Third-Party Payors), and private individuals (Patients). Patients include those without prescription drug insurance coverage (including elderly patients who make payments for drugs that are not covered under the Medicare program) and those who make co-payments under a Third-Party Payor plan or under Medicare Part B.

3. Prescription drugs are an increasingly important part of life for most Nevada citizens. The development of new drugs can benefit Patients through better overall health, avoidance of more expensive surgical procedures, and, in some cases, longer life. Because many Patients must consume prescription drugs to live or function normally, Patients often have no choice but to pay whatever price (or co-pay) that is necessary to obtain their medications.

4. In economic terms, this means that demand for some prescription drugs is highly inelastic: the quantity demanded does not drop significantly even if prices rise. Drug manufacturers, therefore, spend enormous sums to develop and market new drugs, recognizing that they likely will be able to charge prices that will ultimately generate substantial profits for their investors. Of course, if this profit incentive was completely removed, much of the research and development that now takes place would vanish. Thus, the optimal market would both reward innovative drug manufacturers and keep prices as affordable as possible. Balancing these worthwhile goals can be difficult and, unfortunately, abuses take place that have unfairly gouged

Patients and injured the State and its Medicaid program as described below. The Attorney General seeks to enjoin and remedy these abuses.

A. Defendants' Unlawful Schemes

5. Private and public drug reimbursement systems, including private insurance companies, Medicare, and Medicaid, reimburse physicians and pharmacies for hundreds of prescription drugs based upon the Average Wholesale Price ("AWP"), as published and reported by third-party publications such as *First DataBank*, *Red Book*, *Blue Book*, or *Medispan* (the "Publishers").

6. AWPs are not independently determined by the Publishers. Rather, as part of the AWP Inflation Scheme described in this Amended Complaint, pharmaceutical companies "self-report" the AWP to Publishers, who then publish the purported AWP exactly as provided to them by the pharmaceutical manufacturers.

7. As extensive government investigations have recently revealed, numerous pharmaceutical manufacturers (including each of the defendants named herein) have engaged in a scheme (the "AWP Inflation Scheme") involving the fraudulent reporting of fictitious AWPs for certain prescription pharmaceuticals. More specifically, defendants have reported fictitious and fraudulent AWPs that, in many instances, greatly exceeded the average of the wholesale prices based upon a good faith and reasonable estimate utilizing the pricing and transaction information available to defendants in conducting their ordinary business affairs. Thus, the defendant's AWPs for these drugs bear little or no relationship to any purchase price at which a provider or pharmacy is able to procure these drugs.

8. Because prescription drugs are priced based on the published AWPs within the various reimbursement systems, defendants inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients, their insurers and other end payors, including Medicaid. This, in turn, motivates the providers to sell and administer the drugs with the most inflated AWPs, resulting in increased market share and profit for the defendants and inflated payments for drugs by health plans (Medicare, Medicaid, and

other Third-Party Payors including insurers) and individual Patients (through co-pays or direct payments).

9. In some cases, defendants also provide chargebacks, credits, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples, that are not included in the AWPs reported by defendants, which consequently further increase the provider's spread and their incentive to prescribe a particular defendant's product.

10. Thus, in a perversion of the type of competitive behavior expected in a market not subject to illegal manipulation, defendants often promote their drugs not based on lower prices, but by the use of reimbursement rates based on a fictitious and inflated AWP that allows purchasers and intermediaries to make inflated profits – and defendants to increase their market share – at the expense of various reimbursement programs and Patients.

11. In addition, pharmaceutical manufacturers wishing to participate in state Medicaid programs are required by federal law to enter into a rebate agreement with the Secretary of Health and Human Services. Pursuant to these agreements, the manufacturers are obligated to report, on a quarterly basis, their "Best Price" for each drug. The Best Price, which is defined as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity," then forms the basis for refunds, if any, due the Medicaid program.

12. Manufacturers have misrepresented their Best Prices by failing to accurately account for their practices of offering free goods, volume discounts, credits, rebates, educational grants and other programs that lower the providers' actual cost of the drugs. This has resulted in the Best Price being understated, thereby depriving the state Medicaid programs of their full rebates (the "Best Price Scheme").

B. The Damages Caused By Defendants' Illegal Conduct

13. The intended and foreseeable consequences of defendants' unlawful conduct are several and far reaching, including but not limited to increased drug costs to the State of Nevada and its agencies, and increased drug costs to Patients who are Nevada residents.

1. Damages to the State of Nevada

14. One of the foreseeable and intended consequences of defendants' conduct has been to unjustly enrich the defendants at the expense of Nevada's health care system, the state health care authority, and ultimately, all Nevada residents and taxpayers.

15. In particular, the AWP Inflation Scheme and Best Price Scheme have cost the State of Nevada millions of dollars in excess Medicaid payments made for medications as a direct result of the illegal AWP Scheme.

16. In addition, the AWP Inflation Scheme has cost the State of Nevada millions of dollars in excess drug costs for the public employees for whom it provides health care.

17. Finally, numerous state agencies purchase medications at illegally inflated prices based on the AWP Inflation Scheme.

18. The State seeks to recover these costs as actual damages and/or restitution in this case.

2. Damages to Patients

19. As further intended and foreseeable effects of the defendants' AWP Inflation Scheme, many Patients residing in Nevada also suffered losses.

20. The general public, who must make co-payments for drugs based upon these inflated AWP prices, suffered immense damages. A major group of consumers adversely impacted by this practice are the elderly, who make co-payments as part of Medicare. Other harmed consumers include those Nevada citizens who make drug co-payments under third-party health insurance contracts.

21. Through its *parens patriae* and statutory powers, the State of Nevada also seeks restitution of these losses in this case.

C. The Objectives of This Action

22. In this action, the Attorney General seeks to secure for the people of the State of Nevada a fair and open market, free from unfair or deceptive acts or practices, and to enable Patients in this State to better shoulder the financial burden of necessary medications.

23. In addition, the Attorney General brings this action to return to the State and its resident Patients the increased medication costs caused by defendants' wrongful conduct and to disgorge defendants' excessive profits from the AWP Inflation Scheme and the Best Price Scheme accomplished through violations of state law.

II. PARTIES

A. Plaintiff

24. This action is brought for and on behalf of the State of Nevada and damaged persons and entities within the State of Nevada, by Brian Sandoval, Attorney General of the State of Nevada, pursuant to, *inter alia*, the provisions of the Nevada Deceptive Trade Practice Act, NRS 598.0903 *et seq.*, Nevada's Civil RICO statute, NRS 207.470 *et seq.*, Nevada's Medicaid Fraud Statutes, NRS 422.540-.580 and the common law and statutory authority of the Attorney General to represent the State of Nevada and its residents.

B. Defendants

25. The acts charged in this Amended Complaint as having been done by the Defendants were authorized, ordered, or done by their officers, agents, employees, or representatives while actively engaged in the management of the defendants' business or affairs.

26. At all times relevant hereto, each of the defendants transacted business in the State of Nevada, including but not limited to, selling and distributing products in the State.

1. Amgen

27. Defendant Amgen Inc. ("Amgen") is a Delaware corporation with its principal place of business at One Amgen Drive, Thousand Oaks, California. Amgen is a biotechnology corporation that focuses its research and development efforts on drugs related to nephrology, cancer, inflammation, neurology and metabolism. In 2000, Amgen's revenues exceeded $3.6 billion.

28. Amgen manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

2. AstraZeneca

29. Defendant Zeneca, Inc. ("Zeneca") is a Delaware corporation with its principal place of business at Malvern, Pennsylvania. Zeneca is a wholly owned subsidiary of AstraZeneca PLC, a limited liability company domiciled in the United Kingdom.

30. Defendant AstraZeneca US is a Delaware corporation with its principal place of business at 1800 Concord Pike, Wilmington, Delaware.

31. Defendant AstraZeneca Pharmaceuticals L.P. is a Delaware corporation, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca Pharmaceuticals L.P. is owned and controlled by AstraZeneca PLC, a public limited liability company domiciled in the United Kingdom.

32. AstraZeneca PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and AstraZeneca U.S. are collectively referred to as "AstraZeneca." AstraZeneca reported annual sales of $16.5 billion in 2001, with an operating profit of $4.2 billion.

33. AstraZeneca manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

3. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

34. Defendant Aventis Pharmaceuticals, Inc. ("Pharma") is a Delaware corporation with its principal place of business located at 300-400 Somerset Corporate Blvd., Bridgewater, New Jersey. Pharma is a wholly owned subsidiary of Aventis, S.A., a company domiciled in France. Pharma is comprised of the U.S. commercial operations of predecessor companies Rhone-Poulenc Rorer, S.A. and Defendant Hoechst Marion Roussel, Inc. ("Hoechst"). Prior to its acquisition by Pharma, Hoechst was a Delaware corporation with its principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri.

35. Pharma's principal business activities are the discovery, development, manufacture and sale of prescription pharmaceuticals in the areas of cardiology, oncology, infectious diseases, arthritis, allergies and respiratory disorders, diabetes and central nervous system disorders. Pharma reported U.S. net sales of approximately $5.8 billion in 2001.

36. Defendant Aventis Behring L.L.C. ("Behring"), located at 1020 First Avenue, King of Prussia, Pennsylvania, formerly did business as Centeon L.L.C., a 50/50 joint venture between Hoechst and Rhone-Poulenc Rorer, S.A. When Centeon L.L.C.'s parent companies merged to create Aventis in 1996, Behring became its wholly-owned subsidiary.

37. Behring is the plasma protein business of Pharma, producing a line of therapies including coagulation therapies for the treatment of hemophilia, wound healing agents used during major surgical procedures, inhibitor treatments that inhibit the formation of blood clots, immunoglobulins for the prevention and treatment of immune disorders, and plasma expanders for the treatment of a variety of conditions such as shock, burns and circulatory disorders. In 2000, Behring held assets estimated at $1.5 billion.

38. Pharma, Hoechst and Behring are collectively referred to as the "Aventis Group."

39. The Aventis Group manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

4. The Boehringer Group (Boehringer, Ben Venue, Bedford)

40. Defendant Boehringer Ingelheim Corp. ("Boehringer") is a Nevada corporation with its principal place of business located at 900 Ridgefield Road, Ridgefield, Connecticut. Boehringer is a United States subsidiary of Pharma Investment Ltd., of Burlington, Canada, which in turn is a division of C.H. Boehringer Sohn Gurdstucksverwaltung GmbH & Co. KG of Ingelheim, Germany.

41. Defendant Ben Venue Laboratories Inc. ("Ben Venue") is a Delaware corporation with its principal place of business located at 300 Northfield Road, Bedford, Ohio. Ben Venue is a wholly owned subsidiary of Defendant Boehringer.

42. Defendant Bedford Laboratories ("Bedford") is a division of Ben Venue with its principal place of business located at 300 Northfield Road, Bedford, Ohio. Bedford manufactures and markets injectable pharmaceuticals.

43. Boehringer, Ben Venue and Bedford are collectively referred to herein as the "Boehringer Group."

USA was a wholly-owned subsidiary of Fujisawa Pharmaceutical Co. Ltd. In 1998, Fujisawa Healthcare assumed responsibility for Fujisawa USA's portfolio of proprietary products.

50. Fujisawa Healthcare and Fujisawa USA are collectively referred to as "The Fujisawa Group."

51. The Fujisawa Group manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

7. Immunex

52. Defendant Immunex Corporation ("Immunex"), a wholly owned subsidiary of Defendant Amgen, Inc., is a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington. Immunex is a company that develops products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. In 1999, its total revenues were $542 million.

53. Defendant Immunex has been a wholly owned subsidiary of Defendant Amgen, since Immunex' acquisition in July 2002.

54. Immunex manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

8. The Johnson & Johnson Group (J&J, Centocor, Janssen, McNeil, Ortho)

55. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. In 2001, pharmaceutical sales represented 45% of J&J's worldwide sales and 19% of its operational growth.

56. Defendant Centocor, Inc. ("Centocor") is a Pennsylvania corporation and has been a wholly owned subsidiary of Defendant J&J since its acquisition by J&J in October 1999. Centocor's principal place of business is located at 200 Great Valley Parkway, Malvern, Pennsylvania.

57. Defendant Janssen Pharmaceutica Products, L.P. ("Janssen") is a New Jersey limited partnership with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is a subsidiary of J&J.

58. Defendant McNeil-PPC, Inc., is a New Jersey corporation. McNeil-PPC, Inc. is a subsidiary of J&J. McNeil Consumer & Specialty Pharmaceuticals is a division of McNeil-PPC, Inc. and has a principal place of business located at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034.

59. Defendant Ortho Biotech ("Ortho") is New Jersey corporation and has been a wholly owned subsidiary of Defendant J&J since its formation by J&J in 1990. Ortho's principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey.

60. The Johnson & Johnson Group manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

9. Novartis

61. Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a New Jersey corporation with its principal place of business at One Health Plaza, East Hanover, New Jersey. Novartis is a U.S. affiliate of Swiss-based Novartis AG, which reported a net income of $4.2 billion on sales of $19.1 billion in 2001.

62. Novartis manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

10. Pfizer

63. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues, or market capitalization.

64. Pfizer manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

11. The Schering-Plough Group (Schering Plough & Warrick)

65. Defendant Schering-Plough Corporation ("Schering-Plough") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering-Plough's primary business involves prescription products in core product categories, including allergy and respiratory, anti-infective and anti-cancer, cardiovasculars, dermatologicals and central nervous systems and other disorders. Schering-Plough's revenues in 2001 totaled $9.8 billion.

66. Defendant Warrick Pharmaceuticals Corporation ("Warrick"), is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada. Warrick is a wholly-owned subsidiary of Defendant Schering-Plough and has been since its formation in 1993. Warrick manufactures generic pharmaceuticals.

67. Schering-Plough and Warrick are collectively referred to as the Schering-Plough Group.

68. The Schering-Plough Group manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

12. The Sicor Group (Sicor and Gensia)

69. Defendant Sicor, Inc. ("Sicor") is a Delaware corporation with its principal place of business located at 19 Hughes, Irvine, California. Sicor was the result of the 1997 merger between Defendant Gensia, Inc. ("Gensia"), a finished dosage manufacturer, and Rakepoll Holding, a Europe-based supplier of active pharmaceutical ingredients.

70. Sicor markets itself as a vertically-integrated specialty pharmaceutical company with expertise in the development, manufacturing and marketing of injectable pharmaceutical products, primarily used worldwide by hospitals. Sicor's finished dosage products manufacturing operations account for 32% of its total revenue, and is comprised of a portfolio of products that includes oncology, anesthesiology, and critical care. Sicor's 2001 revenues totaled nearly $370 million. According to its website, Sicor operates its business through several subsidiaries.

71. Defendant Gensia Sicor Pharmaceuticals, Inc. ("Gensia Sicor"), a Delaware corporation, is a wholly-owned subsidiary of Sicor with its principal place of business located at 17 Hughes, Irvine, California. Gensia Sicor focuses on acute-care multisource products in the fields of oncology, cardiology and anesthesiology, and its injectable drug business includes more than 60 products.

72. In 1999, Gensia Sicor entered into a sales distribution agreement with Abbott Laboratories under which the two companies formed a strategic alliance for the marketing and distribution of oncology products in the U.S. The agreement was restructured in March 2002. In 1999, Gensia Sicor also amended an earlier agreement with Baxter Pharmaceutical Products, Inc. Notably, Abbott (6%) and Baxter (34%) accounted for nearly 40% of Sicor's total product sales in 2001.

73. Sicor, Gensia and Gensia Sicor are collectively referred to as "The Sicor Group."

74. The Sicor Group manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

13. Watson

75. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California. Watson develops, manufactures and markets brand and generic pharmaceuticals.

76. Watson manufactures several drugs reimbursed by the Nevada Medicaid Program and which are purchased by citizens of the State of Nevada.

III. PRESCRIPTION DRUG SPENDING IN THE UNITED STATES HAS INCREASED DRAMATICALLY, DISPROPORTIONATELY IMPACTING THE POOR AND ELDERLY

77. Prescription drug costs have dramatically escalated over the last decade, with important impacts on government health programs (including Medicare and Medicaid), employers and patients (and particularly elderly patients).

A. Increases in Prescription Drug Costs Generally

78. In 1998, spending on prescription drugs totaled $91 billion in the United States and is projected to reach approximately $243 billion in 2008. THE KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS: A CHARTBOOK at 20 (July 2000) (hereinafter "CHARTBOOK"). In 1999, spending for prescription drugs was $99.6 billion. THE KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS: A CHARTBOOK UPDATE at 5 (November 2001) (hereinafter "CHARTBOOK UPDATE")

79. The growth in prescription drug costs has been staggering. For each year from 1990 to 1998 (excluding 1993 and 1994), prescription drugs costs grew more than 10% annually. CHARTBOOK at 20, 22. Projected prescription drug spending of $116.9 billion in 2000 is nearly double the amount spent in 1995. CHARTBOOK UPDATE at 5.

80. In the last decade, annual growth in prescription drug costs has significantly outpaced spending for other health care categories, including physician services and hospital care. For example, in 1998 prescription drug expenditures increased 15% compared to 5% for physician services and 3% for hospital care. CHARTBOOK at 20. Since 1995, the annual percent increases in spending for prescription drugs have been more than double those for hospital care and physician services. CHARTBOOK UPDATE at 5.

B. Impacts on Medicaid Programs

81. Similarly, spending for prescription drugs by the Medicaid Program has been growing faster than Medicaid spending for other services. For example, from 1990 to 1998, Medicaid spending on prescription drugs increased an average of 14.8% each year, compared to 11.1% for other acute care and 9.1% for long-term care. CHARTBOOK UPDATE at 6.

82. More than 75% of Medicaid prescription drug expenditures were spent for the blind, disabled and the aged. CHARTBOOK UPDATE at 6.

83. Medicaid provided drug coverage for 10% of the Medicare population in the Fall of 1999, as 53% of Medicare beneficiaries with incomes below the federal poverty level are on

Medicaid. THE KAISER FAMILY FOUNDATION, MEDICARE AND PRESCRIPTION DRUGS FACT SHEET at 1 (April 2003).

C. Impacts on the Medicare Program and the Elderly

84. Overall prescription drug spending in the Medicare Program – even ***without*** considering proposals to expand Medicare drug coverage – is projected to rise from $71 billion in 2001 to $228 billion in 2011. CHARTBOOK UPDATE at 6.

85. The increases in prescription drug costs have impacted seniors (defined as age 65 or older) disproportionately because older Americans spend more on prescriptions, both in dollar terms and as a proportion of total household budgets. In 1999, seniors spent nearly twice as much for prescription drugs as did non-seniors. CHARTBOOK UPDATE at 7. In 1998, the proportion of annual total household expenses that consumers aged 65 or older spent out-of-pocket on drugs was over twice as large as that for the next youngest age group (55 to 64 years old) and almost three times as large as the average for all consumers. CHARTBOOK at 24.

86. Seniors spend more out-of-pocket on prescription drugs than the non-elderly because seniors have more acute and chronic health conditions and use more prescription drugs to treat them. Seniors are also less likely to have insurance coverage for prescription drugs. CHARTBOOK at 24.

87. While Medicare beneficiaries constitute just 13 percent of the U.S. population, they account for approximately 36 percent of total outpatient prescription drug expenditures. Most of those covered by Medicare have only moderate incomes: 45 percent have incomes below 200 percent of the poverty level, which equates to approximately $15,000 for an individual and $20,000 for a couple.

88. As this Amended Complaint demonstrates, the frauds contested here have contributed to the surge in spending on prescription drugs.

IV. THE PRESCRIPTION DRUG MARKET

89. In order to better understand the frauds and schemes contested in this lawsuit, it is necessary to briefly review the structure of the prescription drug industry, including the

distribution channel and prescription drug pricing conventions and terminology. Like many industries, the pharmaceutical industry has its own specialized vocabulary.

A. Drug Classifications (Brand Name and Generic)

90. Prescription drug manufacturers generally fall into one of two categories: (i) major pharmaceutical companies that emphasize research and development and the sale of brand name drugs (although these companies may also sell generic drugs), and (ii) generic manufacturers.

91. A "brand name" drug is a patented drug that is manufactured and sold exclusively by one firm (or other companies via a license received from the patent-holder). After the patent expires for a brand name drug, multiple companies can produce the drug, even though the brand name is still used to refer to the original manufacturer's product.

92. Conversely, a "generic" drug is a drug that is no longer covered by patent protection and can consequently be produced and distributed by any company that wishes to do so. Generics are sometimes referred to as multi-source drugs.

93. Thus, a brand name drug may or may not have a generic equivalent, depending upon whether the patent has expired and whether a generic manufacturer has produced a generic version. For example, TAP and Abbott's Prevacid, a popular anti-ulcerant (proton pump inhibitor), is under patent and has no generic equivalent. Tagamet (histamine-2 receptor antagonist) is another drug used to treat ulcers but is no longer protected by patent. It has a generic equivalent named Cimetidine.

B. The Distribution Channel

1. Wholesalers

94. The drug manufacturers distribute their prescription drugs predominantly through wholesalers, although the manufacturers also distribute prescription drugs to some large retailers, hospitals, providers and managed care organizations.

95. As of 1998, roughly 80% of prescription drugs were sold to wholesalers who act as "middlemen" in the distribution chain. CHARTBOOK at 20. The drug wholesaler industry is

very concentrated, with three wholesalers commanding roughly 90% of the market. They are: AmeriSource-Bergen, McKesson and Cardinal Health.

96. The price that a drug manufacturer charges to the wholesaler, before discounts, is known in the industry as the *wholesale acquisition cost* or "WAC."

97. Wholesalers typically price prescription drugs using one of two approaches (both of which could yield a similar price): (i) "Cost Plus," which is the WAC plus a markup percent; and (ii) "List Less" which is the "*average wholesale price*" ("AWP") less a discount percent. AWP is intended to be a national average of list prices charged by wholesalers to pharmacies and, with few exceptions, constitutes the manufacturer's suggested list price for a wholesaler to charge a pharmacy for a drug. As discussed in more detail below, AWP forms the reimbursement foundation in private insurance systems as well as in government reimbursement systems such as Medicare and Medicaid, including the Nevada Medicaid Program.

2. Retail pharmacies

98. Although most retailers obtain their prescription drugs from wholesalers, in 1998 drug manufacturers sold 12.4% of their prescription drugs directly to retailers, including independent pharmacies, chain drugstores and chain warehouse operations. CHARTBOOK at 65, 73.

99. The price charged by a drug manufacturer, before discounts, for drugs sold directly to non-wholesale accounts such as retailers is called the *direct price* ("DP").

100. The cost to a pharmacy of a prescription drug is typically referred to as *actual acquisition cost* ("AAC"). If the pharmacy purchases directly from a manufacturer, the AAC will equal the DP.

101. In selling to the uninsured and to indemnity-insured consumers (where the consumers pay for the drug and then submit a reimbursement request to their insurer), pharmacies typically pay a price based directly or indirectly on the AWP.

102. In selling to other categories of insured consumers (typically the consumer who makes a specified copay in dollar terms (*e.g.*, $10 per prescription) or a coinsurance amount

(*e.g.*, 20% of the prescription price)), the pharmacy charges the consumer based on the insurer's payment formula plus what the insurer allows for a professional dispensing fee. The insurer's payment formula is typically based on AWP less a certain discount for brand name drugs, and a maximum allowable cost ("MAC") plus a dispensing fee for generics.

103. Many health plans, HMOs and employers contract with Pharmacy Benefit Managers ("PBMs") to process pharmaceutical claims and manage drug utilization and "formularies," which are listings of drugs that may be dispensed under a particular plan. The PBMs never actually take possession of prescription drugs (except for drugs that they sell through their in-house mail order operations), but manage delivery of the drug "benefit" through relationships with drug manufacturers and retail pharmacies. For brand name drugs, PBMs often reimburse retail pharmacies at a rate equal to 12 to 13 percent off AWP plus a dispensing fee. For generic drugs, PBMs typically reimburse retail pharmacies at MAC based on the PBM's own estimate of what pharmacies pay on average for the generic drug, plus a dispensing fee.

3. Physicians and others

104. In 1998, drug manufacturers sold the remaining 6.6% of their prescription drugs directly to hospitals (2.6%), physicians and others (4%), including home health care companies. CHARTBOOK at 65, 73.

105. Like the price directly charged by the drug maufacturer to chain pharmacies, the price charged by a drug manufacturer, before discounts, for drugs sold directly to hospitals, private practice physicians and public health clinics is the DP.

106. Physicians and hospitals are most frequently reimbursed based on AWP for the drugs that they provide to privately-insured patients, as well as those patients participating in government-sponsored prescription drug programs.

V. GOVERNMENT REIMBURSEMENT SYSTEMS FOR PRESCRIPTION DRUGS

A. The Medicare Insurance Program

107. In 1965, Congress established the Medicare Program – known officially as "Health Insurance for the Aged and Disabled" – by adding Title XVIII to the Social Security Act.

108. The United States Department of Health & Human Services ("DHHS") is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), is a division of DHHS and is directly responsible for the administration of the Medicare Program.

109. The Medicare Program generally does not cover the cost of prescription drugs that a Medicare beneficiary self-administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare "Part B" does cover some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. All United States citizens and permanent residents aged 65 or older are eligible for Part B coverage.

110. More specifically, Part B covers drugs and biologicals that are not usually self-administered by the patient and are furnished as an incident to a physician's professional services, antigens prepared by a physician for a particular patient, blood clotting factors for hemophilia patients, immunosuppressant therapy drugs furnished to an individual who receives an organ transplant, erythropoietin ("EPO") self-administered by dialysis patients, oral anti-cancer drugs, oral anti-emetic drugs in conjunction with chemotherapy treatments. CCH, 2003 MEDICARE EXPLAINED, ¶ 350 at 92-93 (hereinafter "MEDICARE EXPLAINED"). Approximately 450 drugs are covered by Medicare Part B.

111. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug. During the period 1992 through 1997, Medicare's reimbursement for covered drugs

was set at the lesser of (i) the estimated acquisition cost, or (ii) national average wholesale price. For generic drugs, payment was based on the lower of the estimated acquisition cost or the wholesale price that was defined as the median price for all sources of the generic form of the drug. This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

112. The estimated acquisition cost for a drug could be determined by the Medicare Program "based on surveys of the actual invoice prices paid for the drug" taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

113. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

114. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that reimbursement for certain Medicare Part B drugs and biologicals "are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span."

115. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP.

116. There are no regulations describing how AWPs are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWPs directly

to the federal government, but – as discussed in greater detail below – instead send their pricing information to independent publishing companies that compile the data and publish the AWPs in trade publications, which are then used by the government, as well as private health plans.

117. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable.

118. Some Medicare beneficiaries are able to purchase private Medigap insurance, which covers, among other things, all or part of the 20% co-payment for covered drugs.

B. The Medicaid Insurance Program

119. Nationwide in 1998, Medicaid covered 40.4 million people at some time during the year at a cost of $176.9 billion. BRIAN K. BRUEN, MEDICAID AND PRESCRIPTION DRUGS: AN OVERVIEW at 1 (October 2000) (prepared for the Kaiser Commission on Medicaid and the Uninsured) (hereinafter "MEDICAID AND PRESCRIPTION DRUGS"). In 1995, Medicaid covered about 55% of the nonelderly poor. *Id.* at 1.

1. Eligibility

120. Most people eligible for Medicaid fall into one of the following categories: (i) low-income families with children who meet the eligibility requirements for the Aid to Families with Dependent Children ("AFDC") program; (ii) aged, blind and disabled people who receive Supplemental Security Income ("SSI"), with some exceptions; (iii) low-income pregnant women and children who do not qualify under the AFDC rules because their income is too high or they fail to meet categorical restrictions, but whose incomes do not exceed established limits; (iv) the "medically needy," who are people with higher income or greater resources than the financial standards allow, but who meet certain categorical standards by, for example, incur medical expenses that reduce their excess income or resources to required levels; and (v) people requiring institutional long-term care. *Id.* at 1-2.

121. Although coverage for outpatient prescription drugs is an optional benefit within Medicaid, all Medicaid Programs, including Nevada's, offer prescription drug coverage. *Id.* at 2.

122. Nationwide, Medicaid spent $14.5 billion for prescription drugs. THE KAISER COMMISSION ON MEDICAID AND THE UNINSURED, MEDICAID FACTS: MEDICAID AND PRESCRIPTION DRUGS at 1 (October 2000). In 2000, the Nevada Medicaid Program spent $50,370,705 for prescription drugs, representing 8.4% of the program's total net expenditures.

123. Medicare beneficiaries who have low incomes and limited resources may also be covered by Medicaid as "dual eligibles." For dual eligibles who are eligible for full Medicaid coverage, Medicaid supplements Medicare by providing services and supplies not covered by Medicare, most notably prescription drugs and long-term care services. Medicaid pays monthly Medicare premiums, deductibles and coinsurance for those with incomes below the FPL who do not qualify for full Medicaid benefits, while other Medicare beneficiaries with incomes up to 175 percent of the FPL receive assistance with all or part of their monthly Medicare Part B premiums.

2. Medicaid prescription drug coverage and payment policies

124. The Nevada Medicaid Program covers prescription drugs, which are defined by federal regulation as simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease or for health maintenance that are prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice on a written prescription that is maintained in the pharmacist's or practitioner's records. 42 C.F.R. § 440.120.

125. Nevada provides prescription drug coverage to categorically needy (AFDC-related, aged, blind, disabled) eligible individuals.

126. Medicaid payments for outpatient prescription drugs include two components: acquisition costs and dispensing fees. The Nevada Medicaid program presently reimburses for outpatient drugs on the basis AWP less 10% plus a $4.76 dispensing fee. NEVADA MEDICAID SERVICES MANUAL § 1204.2. For generic drugs for which Federal Upper Limits ("FUL") have

been set by HCFA, the reimbursement amount is the FUL plus a $4.76 dispensing fee. *Id.* The Nevada Medicaid Program uses the AWP as reported by *First DataBank*.

VI. AWP PLAYS A CENTRAL ROLE IN ALL PRESCRIPTION DRUG REIMBURSEMENT SYSTEMS, AND THE TRUTHFUL REPORTING OF AWPS IS ESSENTIAL TO THE INTEGRITY OF THE MARKETPLACE

127. As demonstrated above, AWPs play a very important role in the various prescription drug pricing and reimbursement systems that operate in the United States.

128. There are approximately 65,000 different drug products in the United States, including different dosages of the same drug. Prescription drugs are dispensed to Patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) hospitals, (c) retail pharmacies, (d) home infusion pharmacies, and (e) other medical providers. Reimbursements and end-payor payments for those drugs are almost always based on AWP.

129. Providers and pharmacies regularly submit claims for reimbursement, seeking reimbursement for the drugs from Medicare, Medicaid, insurers and Patients. Defendants were and are well aware that various participants in these systems rely on AWPs to reimburse providers and pharmacies for prescription drugs: private insurance companies (such as Blue Cross and Blue Shield Plans); health maintenance organizations and other managed care organizations; self-insured employers and other health plans such as union health and welfare plans; PBMs who administer the pharmacy benefit for private plans; Medicare; and Medicaid, including the Nevada Medicaid Program. In short, use of the published AWPs to establish reimbursement rates for drugs ***is an industry-wide practice*** and exists with respect to all classes of drugs, brand name and generic.

130. There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs on the market, including the *Drug Topics Red Book* (the "*Red Book*"), *American Druggist First DataBank Annual Directory of Pharmaceuticals, Essential Directory of Pharmaceuticals* (the "*Blue Book*")

and Medi-Span's *Master Drug Database* (collectively referred to herein as the "Publishers"). These Publishers publish AWPs for the various dosage forms for drugs.

131. In periodically announcing the AWP for each drug, and during the time period relevant to this Amended Complaint, the Publishers published the prices that are supplied to them by the defendants for their respective drugs. For instance, the forward to the 1999 edition of the *Red Book* states that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the defendants control the prices listed as the AWPs for each drug listed by the Publisher. As one defendant, Dey, has admitted in court papers:

> Virtually every drug manufacturer who participates in these reimbursement programs, and against whom Dey competes also communicates their suggested AWP prices to the reporting services. To the best of Dey's knowledge, with few, if any exceptions, First DataBank and Medi-Span have selected and reported the AWP pricing exactly as suggested by these competing manufacturers.

(Dey, L.P. v. First Databank and Wolters Kluwer Health, Inc. d/b/a Medi-Span, Complaint (the "Dey Complaint"), ¶ 37.) *See also* ¶ 47 of Dey Complaint (recounting testimony of First DataBank representative who admits that First DataBank had always accepted the AWPs suggested by the manufacturers).

132. A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers. Defendants knew they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP. Defendants also knew that actual transaction price data – the amounts charged to providers and others for their drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret.

133. The importance of accurately reported AWPs was recently reconfirmed by the HHS Office of the Inspector General ("OIG") in an April 2003 report titled COMPLIANCE

PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS ("OIG COMPLIANCE PROGRAM"). The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate" and made clear that the AWP must be a meaningful figure that is not artificially inflated:

> Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act . . . if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly . . . failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute.
>
> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements. [OIG COMPLIANCE PROGRAM at 11-12.]

134. And, the OIG rejected the notion that purposeful AWP manipulation to create "spreads" was a lawful practice:

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill

> the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.*** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [OIG COMPLIANCE PROGRAM at 26-27.] [Emphasis added.]

135. As detailed below, defendants have taken advantage of this system in a fraudulent and otherwise unlawful manner to manipulate the AWPs for their drugs at the expense of numerous prescription drug payors including the Nevada Medicaid Program.

VII. THE AWP INFLATION SCHEME

136. The AWPs for the drugs at issue here bore little relationship to the drugs' pricing in the marketplace. Defendants simply fabricated and overstated their AWPs in furtherance of a

scheme to generate profit spreads to providers, PBMs and others and to increase defendants' profits at the expense of Patients and programs such as the Nevada Medicaid Program.

137. Defendants' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs (sometimes referred to herein as the "AWP Inflation Scheme") directly caused the State of Nevada to substantially overpay for those drugs. Furthermore, the AWP Inflation Scheme caused Nevada citizens and Third-Party Payors to pay inflated co-pays or prices for prescription drug purchases.

A. General Outline Of The Scheme For Brand Name Drugs

138. Each defendant perpetrated the alleged fraudulent AWP Inflation Scheme by using some and/or all of the following practices:

1. Artificially Inflating AWPs

139. Each defendant provided AWPs for each of its drugs, both brand name and generic, to *First DataBank*, the *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia.

140. Defendants deliberately and intentionally reported inflated AWPs that greatly exceeded the average of the wholesale prices based upon a good faith and reasonable estimate utilizing the pricing and transaction information available to defendants in conducting their ordinary business affairs. Thus, the defendant's AWPs for these drugs bear little or no relationship to any purchase price at which a provider or pharmacy is able to procure these drugs. Defendants created the AWP Inflation Scheme solely to cause the State of Nevada and others to overpay for the drugs.

141. Defendants created and perpetuated this scheme so that the medical providers and pharmacies who purchased these drugs at a low cost would bill Patients and their insurers at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates established by Medicare, Medicaid and thousands of private health insurance plans.

142. Defendants knew and understood that Medicare, the Nevada Medicaid Program and private payors used the *First DataBank* and other publications to determine the AWPs of the drugs. Because defendants controlled the AWPs published in *First DataBank* and other compendia, defendants knew and understood that they could manipulate the providers' profits. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers and other reimbursement players, funded by overpayments by various reimbursing entities, including the Nevada Medicaid Program, and Patients.

143. As part of their scheme, defendants specifically instructed and expected the providers to charge the inflated AWPs for drugs to Medicare, Medicaid, and Patients making co-payments.

2. Improper Use of Free Samples

144. Defendants, through their sales personnel and marketing representatives, also provided free samples of their drugs to physicians as a means of lowering the price. The free samples were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread." Moreover, defendants specifically told physicians to bill the Nevada Medicaid Program and others for the free samples, which defendants knew was unlawful.

145. Every free sample of a drug for which a provider bills a patient or insurer effectively reduces that provider's overall cost for that drug. However, reimbursing entities, such as the Nevada Medicaid Program, paid the full cost of the drug; the free sample is not used by the drug company in calculating the AWP, which in turn inflates the AWP.

146. Although defendants provided free samples and marketed them as a way to lower the providers' actual cost of the drugs, they did not include the value of the free samples in calculating the AWPs for those drugs. Thus, defendants effectively and improperly passed on the cost of the free samples directly to the State of Nevada, other reimbursing entities and Patients making co-pays.

3. Other Hidden and Improper Inducements and Price Reductions

147. Defendants have also provided and/or arranged for many other non-public financial inducements to stimulate sales of their drugs at the expense of the Nevada Medicaid Program and others. Such inducements included volume discounts, credits, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing defendants' drugs, yet – again – the value of these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflates the AWP.

B. General Outline of the AWP Inflation Scheme for Generic Drugs

148. Defendants' AWP Inflation Scheme is most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents.

149. As with brand name drugs, reimbursement for multi-source, or generic drugs, is also related to a published AWP for each generic drug manufactured and/or distributed by a generic drug company.

150. In the Medicare payor arena, multi-source drugs or biologicals are reimbursed on the basis of AWP. For multi-source drugs or biologicals reimbursed under Medicare Part B, the AWP is equal to the lessor of the median AWP of all of the generic forms of the drug or biological, or the lowest AWP of the brand name product. 42 C.F.R. § 405.517.

151. Under the Nevada Medicaid Program, reimbursement for multiple source drugs for which there are at least three suppliers is equal to (i) a $4.76 dispensing fee, plus (ii) an amount equal to 150 percent of the lowest AWP published by First DataBank, Medi-Span or the *Red Book* (an amount called the "Federal Upper Limit" or "FUL"). 42 C.F.R. § 447.332(b). This calculation is made and published periodically by CMS.

152. Because reimbursement under Medicare and Medicaid is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicaid and Medicare Part B, including the Medicare co-payment through Part B.

153. The raising of an individual defendant's reported AWP for a multi-source drug thus raises the AWP at which the generic drug is reimbursed. In the case of Medicare, raising an individual AWP contributes to a higher median AWP. Under Medicaid, raising an individual AWP increases the FUL if the AWP being raised is the lowest AWP published (unless there are only two suppliers of the generic drug, in which case raising the AWP increases the reimbursement amount correspondingly).

154. Moreover, while any one generic manufacturer can only affect the median generic reimbursement AWP for a product (in the case of Medicare) or the FUL (in the case of Medicaid), defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices ***while simultaneously maintaining or lowering actual wholesale prices***.

155. As stated by one industry consultant:

> . . . Th[e] situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs. . . . [T]he system allows a retailer to acquire a drug at a low cost $2.50 per 100 tablets, for example) while relying on a published AWP ($20.00 or more) for its own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines. . . . It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits.

156. In the private payor arena, generic drug reimbursement is determined either in the same manner for brand name drugs (*i.e.*, a certain percentage "discount" off of the AWP), or is based on an amount specified as the maximum allowable cost or "MAC." MAC prices or reimbursements rates for generically equivalent drugs for which there are three or more suppliers are based upon the FULs issued periodically by CMS.

157. PBMs often utilize this government-issued MAC reimbursement publication as a basis for their proprietary MAC list and supplement the list with other generic products or modify it for a variety of purposes. Sometimes, to stabilize the cost variance of different generic products of the same compound, PBMs calculate a maximum allowable cost based on the list average wholesale prices of competing generic drug manufacturers (indeed, this is termed in the industry as the "average average wholesale price" or "AAWP"). The resulting proprietary MAC generic drug reimbursement lists are typically based on the AAWP and, in turn, the AWP.

158. Accordingly, in the private payor arena generic drug reimbursement is closely tied to the published AWP for a generic drug. Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain, be they pharmacists or physicians. That profit margin is taken advantage of either directly (through reimbursement based upon the AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a MAC tied to the AWP.

159. Documents produced by defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales prices of their generic competitors, and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

Defendant	Multisource Drug	*Red Book* AWP	DOJ Determined Actual AWP	Percentage Spread
Abbott	Sodium Chloride	$670.89	$3.22	20,735%
Baxter	Dextrose	$928.51	$2.25	41,167%
Baxter	Sodium Chloride	$928.51	$1.71	54,199%
Boehringer Group	Leucovorin Calcium	$184.40	$2.76	6,581%